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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,423	07/29/2003	Kiran K. Chada	69014-A/GJG	1805

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EXAMINER	
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ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,423	CHADA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,47,102,103 and 116* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,10-15,47,102,103 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/20/06 and 2/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the election of species requirement received on 5/5/08 has been entered. Claims 1-15, 47, 102-103, and 116 are pending in the instant application. As discussed in detail in the previous office action, applicant's elected with traverse the invention of Group I, claims 1-9, in their response received on 9/28/07. Applicant's traversal was addressed in detail in the action mailed on 4/1/08 and was not found persuasive. The restriction requirement was made FINAL in the 4/1/08 action. In the instant response, the applicant has elected the species of HGMIC -/- and HGMIC -/-/ob/ob mice as the two species of mice whose tissue is to be analyzed. As the applicant has not indicated that this election was made with traverse or presented any arguments traversing this election of species requirement, the election is considered to have been made without traverse. Claims 10-15, 47, 102-103, and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 4, and 6-7 are withdrawn from further consideration as being drawn to non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 9/28/07. Claims 1-3, 5, and 8-9 are therefore currently under examination. An action on the merits follows.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method of identifying genes that are over-expressed in adipose tissue as compared to non-adipose tissue; however, the method comprises a single step of performing differential gene expression analysis between white adipose tissue (WAT) or stromal vascular tissue from various mice species. The claims as written do not include a step where the differential gene expression is analyzed in adipose tissue versus non-adipose tissue. In fact, dependent claim 5 clearly indicates that the differential gene expression analysis is performed between the WAT of HMGI-C -/- mice and the WAT of HMGI-C -/- ob/ob mice, which is a comparison between two different types of adipose tissue. While such analysis might identify genes with differential expression, either up-regulated or down-regulated, in the adipose tissue of two different mice strains, such analysis, in the absence of any additional steps, would not result in the identification of an gene that is over-expressed in adipose tissue versus non-adipose tissue. The claimed methods are therefore confusing as the steps recited in the method as claimed do not result in the function of the method identified in the preamble, i.e. identification of genes over-expressed in adipose tissue compared to non-adipose tissue. As such, the metes and bounds of the claims cannot be determined.

In the interests of compact prosecution, the claims have been examined based on the specific method steps set forth in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukas et al. (2000) Genes and Development, Vol. 14, 963-980, in view of Anand et al. (2000) Nature Genetics, Vol. 24, 377-380. The applicant claims methods of identifying genes that are

over-expressed in adipose tissue as compared to non-adipose tissue comprising performing differential gene expression analysis between the white adipose tissue (WAT) or stromal vascular tissue (SVT) from HMGI-C -/- and HMGI-C -/- ob/ob genotype mice. The applicant further claims said method where the tissue is adipocytes or pre-adipocytes, and wherein the analysis is performed using an Affymetrix GeneChip system. As noted above in the rejection of the claims under 35 U.S.C. 112, second paragraph, the claims as written are confusing since the recited method step does not provide for a comparison of adipose versus non-adipose tissue. However, as previously indicated, in the interests of compact prosecution, the claims have been examined based on the recited method step of performing differential gene expression analysis between the white adipose tissue (WAT) or stromal vascular tissue (SVT) from HMGI-C -/- and HMGI-C -/- ob/ob genotype mice.

Soukas et al. teaches methods of identifying genes differentially expressed in white adipose tissue (WAT), which comprises both adipocytes and pre-adipocytes, of ob/ob mice versus wild-type mice, or ob/ob mice versus ob/ob transgenic leptin mice using microarray gene expression analysis performed using an Affymetrix GeneChip system (Soukas et al., pages 971, and 977-978). Soukas et al. further demonstrates the successful identification of a number of differentially expressed genes in the WAT of ob/ob mice versus wild type mice (Soukas et al., pages 966, Figure 1, and page 975). Soukas et al. teaches that such differential gene analysis in mouse models of obesity can help to elucidate that genetic pathways and specific genes involved in the development of obesity (Soukas et al., pages 976-977).

Soukas et al. differs from the instant methods by not teaching or suggesting to conduct differential gene expression analysis between the WAT of HMGI-C -/- mice and HMGI-C -/-

ob/ob mice. Anand et al. supplements Soukas et al. by teaching the comparison of various phenotypes and characteristics between HMGI-C -/- mice, ob/ob mice, and HMGI-C- -/- ob/ob double knock-out mice, including appearance, body weight, fat pad weight from different locations, WAT histology, and cell number in various fat pads (Anand et al., pages 378-379, Figures 3-5). Anand et al. further teaches that such analysis demonstrates that HMGI-C has an important role in adipogenesis and obesity, as the lack of HMGI-C expression in HMGI-C -/- ob/ob mice substantially but not totally prevents the development of obesity normally observed in ob/ob mice (Anand et al., pages 378-379). Anand et al. further discloses analyzing the differential expression of various genes in adipocytes from ob/ob or HMGI-C -/- ob/ob mice (Anand et al., page 378). Thus, in view of the teachings of Soukas et al. that differential gene expression analysis in mouse models of obesity such as the ob/ob mouse can elucidate genetic pathways and specific genes involved in adipogenesis and the development of obesity, and the teachings of Anand et al. that comparison of traits in HMGI -/- and HMGI -/- ob/ob mice, including gene expression, can be used to study the genetic basis of obesity, it would have been *prima facie* obvious to the skilled artisan at the time of filing to conduct differential gene expression analysis on the WAT of HMGI -/- and HMGI -/- ob/ob mice in order to identify genetic pathways and specific genes involved in adipogenesis and the development of obesity. Further, based on the successful use of differential gene expression analysis performed using the Affymetrix GeneChip system to identify differentially expressed genes in genetic models of obesity taught by Soukas et al., the skilled artisan would have had a reasonable expectation of success in using the Affymetrix GeneChip system to identify differentially expressed genes in the WAT of HMGI -/- versus HMGI -/- ob/ob mice.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soukas et al. (2000) Genes and Development, Vol. 14, 963-980, in view of Anand et al. (2000) Nature Genetics, Vol. 24, 377-380, as applied to claims 1-3, 5, and 8 above, and further in view of US Patent Application Publication 2002/0155472 A1 (2002), hereafter referred to as Czech et al.

As discussed in detail above, Soukas et al. in view of Anand et al. provides the teachings and motivation to analyze differential gene expression between the WAT of HMGI -/- and HMGI -/- ob/ob mice using the Affymetrix GeneChip system. Neither Soukas et al. nor Anand et al. teaches to use an Affymetrix MG-U74 chip. Soukas et al., it is noted, utilized an Affymetrix Mu6500 GeneChip for the microarray analysis. However, at the time of filing, it was well known that Affymetrix produced more than one mouse genome chip useful for differential gene expression analysis. Czech et al., for example, teaches the successful use of an Affymetrix murine genome U74A, i.e. MG-U74A, GeneChip to detect differential gene expression in adipocytes versus other cell types (Czech et al, pages 21-22). Thus, it would have been *prima facie* obvious to the skilled artisan at the time of filing to substitute the Affymetrix MG-U74A GeneChip taught by Czech et al. for the Affymetrix Mu6500 GeneChip in the methods of Soukas et al. as each GeneChip was art recognized as capable of achieving the predictable result of identifying differentially expressed genes in adipose tissue.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633

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